81885

SEP 17 2002

September 6, 2002

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C Street, SW Washington, DC 20204

Re: Statements of Nutritional Support – Notification

## Dear Sir/Madam:

This letter is submitted by New Vision International Holdings, Inc. ("New Vision"), 1920 East Broadway, Tempe, Arizona 85282, to notify the agency that pursuant to Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 343 (r)(6), statements of nutritional support are being made for dietary ingredients contained in a dietary supplement marketed by New Vision as follows:

## vem vision

## Liquid Essentials for Women

- Specifically designed to meet the nutritional needs of women throughout their reproductive cycle and through the transition of menopause, this formula features black cohosh, an herb used traditionally by Native Americans and over the last half century in Europe for natural relief of PMS and menopause symptoms.
- Relieves symptoms commonly associated with PMS and menopause, including hot flashes, irritability, night sweats and related sleeplessness.
- Includes soy isoflavones and important vitamins B-6, B-12 and folic acid commonly used for symptom relief and nutritional support.
- Nutritional support for relief of PMS and menopause symptoms.
- Provides relief for hot flashes, irritability, night sweats and related sleeplessness.

#1920 E. Broadway

Tempe, AZ 85282-1702

T. 480.927.8999

F. 480.927.8665

www.newvision.com

Teamwork.

Integrity.

Freedom.

97S 0162 LET //0/0

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800) September 6, 2002 Page 2

- New Vision's Liquid Essentials for Women addresses the specific nutritional needs of women throughout their reproductive cycle and through the transition of menopause.
- A specific blend of targeting ingredients assists in reducing uncomfortable symptoms associated with PMS and menopause.
- This proprietary formula was specifically designed to meet the nutritional needs of women who suffer from the symptoms of menopause and PMS.
- Experience natural relief of the uncomfortable symptoms often associated with PMS and menopause today!
- Helps relieve symptoms commonly associated with PMS and menopause.
- Designed to meet the needs of women of all ages, especially those looking for relief of symptoms commonly associated with PMS and menopause.
- Natural relief of hot flashes, irritability, night sweats and related sleeplessness.
- Liquid Essentials for Women features black cohosh, an herb used traditionally by Native Americans and over the last half century in Europe for natural relief of PMS and menopause symptoms.
- Vitamin B-12 Along with folic acid, provides some of the necessary nutrients for DNA synthesis, nerve cell function and provides heart health benefits.
- Vitamin B-6 This nutrient is needed by the body to make seratonin, melatonin and dopamine that are essential for the regulation of mental processes.

The disclaimer required by FFDCA § 403(r)(6) accompanies each statement of nutritional support.

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800) September 6, 2002 Page 3

The undersigned certifies that the information contained in this notice is complete and accurate, and that New Vision has substantiation that each statement of nutritional support is truthful and not misleading.

Very truly yours,

Lyng McGovern
Marketing Director

LM:at